## BACKGROUND OF THE INVENTION

My invention relates to a patient airway bite block and, more particularly, to a bite block used together with laryngeal mask airways (LMAs), oral endotracheal tubes, and similar patient airways.

In general, patients undergoing general anesthesia must have their airways secured in order to assure adequate ventilation. This is often accomplished through the use of an LMA which functions in place of either a patient face mask or an endotracheal tube. LMAs are comprised of a distal portion which is a cuffed disc-like device which fits around the larynx in the posterior hypopharynx and a more proximal portion which is analogous to an endotracheal tube. LMAs are placed in anesthetized patients blindly and the exiting tube portion is positioned directly in the mid-line of the mouth

Use of an LMA in anesthetized patients poses several serious problems. First, patients may bite down on the tube portion of the device and cause airway obstruction. This can lead very quickly to hypoxemia (i.e., dangerously low levels of oxygen in the blood) of the patient. Second, such biting by the patient's incisors can cause actual severing of the LMA and subsequent loss of control of the airway. Third, secretions tend to accumulate in the back of the throat during general anesthesia because there is a loss of the normal swallowing reflexes in anesthetized patients. In a lightly anesthetized patient, or in a patent that is awakening from general anesthesia, such secretions can cause laryngospasm and subsequent airway closure. The reason that the secretions cause such a reaction is because the airway reflexes are heightened during light stages of general anesthesia. In order to treat laryngospasm, practitioners must use positive pressure ventilation and occasionally are forced to temporarily paralyze patients using neuromuscular blocking drugs. The practitioner can minimize the likelihood of experiencing laryngospasm by suctioning the secretions from the hypopharynx. Because of the above-described problems encountered using an LMA, it is necessary to place a bite block between the teeth of the anesthetized patient.

Conventionally, practitioners have relied on "homemade" solutions to the problem of utilizing a bite block with LMAs. Moreover, bite blocks designed for use with dental patients are inappropriate for use with LMAs because there is no handle attached. If an ordinary bite block is used in anesthetized patients, it could fall into the back of the throat and either cause airway obstruction when the LMA is removed, or be carried into the esophagus and alimentary tract. In addition, since conventional dental bite blocks are made for use in awake patients, they are not strong enough to withstand the tremendous forces which anesthetized patients generate when they involuntarily clench their teeth together.

Conventional oral airways which are used in patients 55 anesthetized with their airway secured with oral endotracheal tubes are likewise not suitable for use with LMAs because such devices seat themselves directly in the midline of the mouth and thus compete for the space where the tube portion of the LMA exits the mouth. In addition, the posterior portion of the oral airway which is used to hold the tongue forward when used with an endotracheal tube impinges on the cuffed portion of the LMA in the hypopharynx and thereby cannot function properly.

Among the solutions practitioners have employed to 65 provide bite blocks for patients with LMAs include the modification of other products which are intended for com-

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pletely different uses. For example, a bite guard for use with gastroscopy patients has been described for use as a bite block. This device is not suitable because (1) it is not designed for use with LMAs and is not sized appropriately, (2) it is a non-disposable item and introduces the problem of the cost of cleaning and possible contamination to other patients, (3) it seats in the center of the mouth, (4) it is not safe for patients with frontal dental bridge work since this is the area that will bite down on the device, and (5) it has no handle and therefore can be easily lost in the back of the patient's throat. Other practitioners have tried to make bite blocks by wrapping gauze over the end of a tongue blade and holding the gauze in place with tape. This likewise is an unsatisfactory solution because of (1) the time required to assemble the device, (2) the difficulty in judging in the appropriate size required for any given patient. (3) the fact that the gauze can easily slip off the end of the tongue blade and be lost in the posterior hypopharynx, and (4) the wooden part of the tongue blade is easily broken.

An alternative to utilizing an LMA to secure the airway in an anesthetized patient is the use of an oral endotracheal tube. These patients also require a device which prevents occlusion or severing of the tube by the patient's incisors, and this is often accomplished by the use of a conventional oral airway. However, in patients who have oral endotracheal tubes in place and also have loose or fragile anterior dental work or loose incisors, biting down on an oral airway can cause damage to such anterior dental structures.

U.S. Pat. No. 4,425,911 (Luomanen et al.) discloses a bite-block for intubated endotracheal tubes. The bite block includes a body having a substantially rectangular cross-section, a face plate joined to the body at the exterior end thereof, and a projection extending laterally from the body on one side thereof. The body is provided with a longitudinally extending centrally located U-shaped channel open at the top, and a pair of continuously extending open-sided U-shaped channels on either side of the center channel. Upper and lower surfaces of the projection extend substantially perpendicular to the side of the main body, with the projection terminating in a flange. Ridges or steps are provided on the upper and lower surfaces and are configured for complementary engagement with the patient's canines, bicuspids and molars.

However, there are a number of drawbacks in the bite block of Luomanen et al. In particular, the upper and lower 45 teeth contacting surfaces are not angled to provide for the jaw to be opened as wide as possible. For this reason, the Luomanen et al. bite block could not function to aid in LMA insertion. Moreover, the face plate of the Luomanen et al. device provides the potential for injury or damage to the incisors or lips by, for example, pressure exerted on the face plate causing the device to be pushed posteriorly and in turn easily damaging the incisors. The face plate also prevents further posterior movement of the device. Further still, the Luomanen et al. device is designed to hold an endotracheal tube precisely and tightly in place, whereas the LMA breathing tube portion requires a slight freedom of movement in order to perform adjustments in the cuff volume thereof. The Luomanen et al. device includes an integral portion designed to keep the tongue from slipping back into the patient's throat. Accordingly, as a patient awakens from a general anesthetic, the device must be removed prior to the return of the pharyngeal reflexes (i.e., gagging, regurgitation, etc.). The Luomanen et al. device lacks any type of handle for positioning and removing the device within and from, respectively, the patient's mouth.

U.S. Pat. No. 2,708,931 (Freedland) and U.S. Pat. No. 2,694,397 (Herms) disclose a mouth guard and a mouth